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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS, and DEBIOPHARM, S.A., Plaintiffs and Counterclaim-Defendants, v. FRESENIUS KABI ONCOLOGY PLC f/k/a DABUR ONCOLOGY PLC and FRESENIUS KABI PHARMA LIMITED f/k/a DABUR PHARMA LIMITED, Defendants and Counterclaim-Plaintiffs.	**CONSOLIDATED UNDER CIVIL ACTION NO. 07-2762(JAP)(JJH)** Civil Action No. 07-02854 (JAP) (JJH)

REPLY MEMORANDUM OF FRESENIUS KABI ONCOLOGY PLC AND FRESENIUS KABI PHARMA LIMITED IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT OF U.S. PATENT NO. 5,290,961 AND IN OPPOSITION TO PLAINTIFFS' CROSS-MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 5,290,961

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Defendants, Fresenius Kabi Oncology plc and Fresenius Kabi Pharma Limited (collectively "Fresenius")[1] respectfully submit this reply memorandum in support of their motion for summary judgment of non-infringement of claim 1 of U.S. Patent No. 5,290,961 ("the '961 patent") and in opposition to the cross-motion of Sanofi-Aventis U.S. LLC, Sanofi-Aventis, and Debiopharm, S.A. (collectively "Sanofi") for summary judgment of infringement of claim 1 of the '961 patent.

INTRODUCTION

Sanofi has conceded that Fresenius does not infringe claim 1 literally; it contends only that Fresenius infringes under the doctrine of equivalents. Bhatt Dec. Ex. 1, Sanofi Response to Interrogatory No. 5[2]; Sanofi Response to Fresenius Statement of Material Fact No. 2. Fresenius submits that there are separate and independently sufficient grounds upon which this Court should grant Fresenius's motion for summary judgment of non-infringement.

First, Sanofi is precluded as a matter of law from relying on the doctrine of equivalents, because (1) the applicants chose to narrowly claim their alleged invention and limited it to processes that include the step of adding sodium iodide and/or potassium iodide to convert compound II, the by-products of compound II, and silver ions to their iodide compounds, followed by removal of the iodide compounds; and (2) the applicants described their alleged invention in terms of a very specific solution (adding sodium iodide and/or potassium iodide to remove compound II, the by-products of compound II, and silver ions) to a very specific problem (the presence of compound II, the by-products of compound II, and silver ions) with a specific prior art process (a process that is identical to the claimed process except for the step of adding

[1] Fresenius Kabi Oncology plc and Fresenius Kabi Pharma Limited were formerly known as Dabur Oncology plc and Dabur Pharma Limited, respectively.

[2] Exhibits designated "Bhatt Dec. Ex." were filed on December 31, 2008 with Fresenius's opening memorandum.

sodium iodide and/or potassium iodide to remove the unwanted compounds). Planet Bingo, LLC v. Gametech International, Inc., 472 F.3d 1338, 1344 (Fed. Cir. 2006), cert. denied, 128 S. Ct. 50 (2007); Cultor Corp. v. A.E. Staley Mfg. Co., 224 F.3d 1328, 1331 (Fed. Cir. 2000). See Section III below.

Second, even if Sanofi were entitled to rely on the doctrine of equivalents – which it is not – for the following reason Sanofi's opposition brief has failed to raise a genuine issue of material fact as to [redacted]

Claim 1 of the '961 patent requires that the iodide compound remove three things from the solution:

> adding to the solution sodium iodide and/or potassium iodide to convert [a] the unreacted compound (II), [b] the by-products of the compound (II) and [c] an unreacted silver ion to their iodine compounds followed by the removal thereof.

The specification states that there was a problem with the prior art process because it did not remove [a] compound II, [b] the by-products of compound II, and [c] silver ions. Bhatt Dec. Ex. 2, '961 patent, col. 1, lines 43-48. The specification goes on to describe the claimed invention as the solution to the problem -- the addition of sodium iodide and/or potassium iodide, which reacts with [a] compound II, [b] the by-products of compound II, and [c] the silver ions to form iodide compounds, which iodide compounds are then removed.

Sanofi's opposition brief (and the supporting Farrell Declaration) argue [redacted]

[redacted] Sanofi does not dispute this -- because it cannot dispute this.

[redacted] "There can be 'no genuine issue as to any material fact' where the nonmoving party's proof is deficient in meeting an essential part of the applicable legal standard, since such failure renders all of the facts immaterial." London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1537-38 (Fed. Cir. 1991) (quoting Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986)).

Finally, Sanofi argues that Fresenius has conceded that the other elements of claim 1 are present in the Fresenius process. This argument is both incorrect (Fresenius has conceded nothing of the sort) and irrelevant. As the accused infringer, Fresenius need only demonstrate that one claim limitation is absent from its process in order to prevail on its non-infringement defense. Therefore, Fresenius's motion focused on the above claim limitation. [redacted] Fresenius need not prevail on this point in order for its motion to be

granted, but it provides an additional basis upon which this Court may rely in denying Sanofi's cross-motion.

ARGUMENT

I.

FRESENIUS DESIGNED AROUND THE '961 PATENT

This case was brought under the Hatch-Waxman statute, a statute that provides a mechanism whereby generic drug companies can file applications for generic versions of brand name drugs. Sanofi listed in the Orange Book patents that it contends would be infringed by a generic drug company seeking approval to sell oxaliplatin products. When Fresenius decided to develop generic oxaliplatin products, it reviewed the Orange Book and identified the listed patents, including the '961 patent. Fresenius then proceeded to "design around" the '961 patent and developed a process for making oxaliplatin that did not infringe. The Federal Circuit has held that "[d]esigning around or inventing around patents to make new inventions is encouraged." London, 946 F.2d at 1538.

> Conduct such as [Fresenius's], involving keeping track of a competitor's products and designing new and possibly better or cheaper functional equivalents is the stuff of which competition is made and is supposed to benefit the consumer. One of the benefits of a patent system is its so-called 'negative incentive' to 'design around' a competitor's products, even when they are patented, thus bringing a steady flow of innovations to the marketplace.

State Industries, Inc. v. A.O. Smith Corp., 751 F.2d 1226, 1235-36 (Fed. Cir. 1985); Westvaco Corp. v. International Paper Co., 991 F.2d 735, 745 (Fed. Cir. 1993) ("Westvaco did not copy IPC's product, but instead attempted to design around IPC's product. Westvaco made specific structural changes to its product so that its product was not a copy of IPC's product."). Therefore, not only is Sanofi's argument that Fresenius "copied" its invention and thus did something wrong nothing more than a rhetorical flourish, it is a legally incorrect rhetorical flourish.

II.

CLAIM 1 REQUIRES THE ADDITION OF SODIUM IODIDE AND/OR POTASSIUM IODIDE TO CONVERT COMPOUND II, THE BY-PRODUCTS OF COMPOUND II, AND SILVER IONS TO THEIR IODIDE COMPOUNDS FOLLOWED BY THE REMOVAL OF THE IODIDE COMPOUNDS

Sanofi argues that "the scope of the claims is not at issue here." Opp. at 12. This statement is incorrect. While Sanofi argues that claim 1 requires that the sodium iodide and/or potassium iodide remove only silver ions, the claim language, specification, and prosecution history demonstrate that the sodium and/or potassium iodide must remove not only silver ions, but also compound II and the by-products of compound II.[3]

A. Claim 1 Recites the Addition of Sodium Iodide and/or Potassium Iodide to Remove Compound II, the By-Products of Compound II, and Silver Ions

Claim 1 of the '961 patent is generally directed to a process for preparing certain compounds, including oxaliplatin. Fresenius can prevail on its motion for summary judgment of non-infringement by demonstrating the absence of just one of the steps of the process. Spectrum Int'l v. Sterilite Corp., 164 F.3d 1372, 1379 (Fed. Cir. 1998) (if the accused product fails to meet even one claim limitation, it cannot infringe the claim). The express language of claim 1 requires that the sodium iodide and/or potassium iodide remove three things:

> 1. A process of preparing a cis-platinum (II) complex of a 1,2-cyclohexanediamine isomer designated by a general formula (I) . . .
>
> which comprises . . . adding to the solution sodium iodide and/or potassium iodide to convert [a] the unreacted compound (II), [b] the by-products of the compound (II) and [c] an unreacted silver ion to their iodine compounds followed by the removal thereof and thereafter adding the corresponding organic dibasic acid of

[3] This dispute does not preclude summary judgment, since claim construction is a legal issue. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976-979 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996); Athletic Alternatives, Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1578 (Fed. Cir. 1996) ("Where, as here, the parties do not dispute any relevant facts regarding the accused product but disagree over which of two possible meanings of claim 1 is the proper one, the question of literal infringement collapses to one of claim construction and is thus amenable to summary judgment.").

> the formulae (V), (VI), (VII), (VIII), (IX) and (X) to the remaining platinum complex.

Bhatt Dec. Ex. 2, '961 patent, Claim 1.

B. The Specification Describes the Addition of Sodium Iodide and/or Potassium Iodide as the Solution to the Problem with the Prior Art Process

The specification of the '961 patent explains the problem with the prior art process: "this preparation process possesses a disadvantage that many impurities such as the unreacted compound (II), compounds (III) and (IV) which are by-products of the compound (II) and an unreacted silver ion remain in the compound (I) prepared according to the above process." Bhatt Dec. Ex. 2, '961 patent, col. 1, lines 43-48. The specification then explains how the alleged invention solves the problem with the prior art process:

> objects can be attained by . . . adding to the solution sodium iodide and/or potassium iodide to covert [sic] the unreacted compound (II), the by-products of the compound (II) and an unreacted silver ion into their iodine compounds followed by the removal thereof.

Bhatt Dec. Ex. 2, '961 patent, col. 2, lines 27-36 (emphasis added).

> such impurities as the unreacted compound (II), the compounds (III) and (IV) are converted into the corresponding iodine compounds by adding sodium iodide and/or potassium iodide thereto.

Bhatt Dec. Ex. 2, '961 patent, col. 2, lines 42-45.

The only example of the claimed invention in the '961 patent describes the addition of potassium iodide to remove compounds II, III, and IV. Bhatt Dec. Ex. 2, '961 patent, col. 3, lines 51-57. Table 1 in the '961 patent specification compares the product made using the claimed invention with the product made using the prior art process in terms of the removal of compounds II, III, and IV. Bhatt Dec. Ex. 2, '961 patent, col. 4. Table 2 in the '961 patent specification compares the processes in terms of the removal of silver ions. Bhatt Dec. Ex. 2, '961 patent, col. 5.

Where the specification describes problems with the prior art and the claimed invention as the solution to those problems, the claims must be interpreted to require a construction that includes that solution. Inpro II Licensing S.A.R.L. v. T-Mobile USA, Inc., 450 F.3d 1350, 1354 (Fed. Cir. 2006); Resqnet.com, Inc. v. Lansa, Inc., 346 F.3d 1374, 1380-81 (Fed. Cir. 2003); Akeva L.L.C. v. Adidas-Salomon, Inc., No. 06-1090, 2006 U.S. App. LEXIS 28195, at *11 (Fed. Cir. Nov. 13, 2006), cert. denied, 127 S. Ct. 2975 (2007).

C. The Examiner Allowed the Claim Because He Understood that the Invention Required the Addition of Sodium Iodide and/or Potassium Iodide

During prosecution, the Examiner stated that he was allowing the claim because it required the addition of sodium iodide and/or potassium iodide, "[c]laim 1 is allowable over the prior art of record. The instant process is novel and unobvious over the prior art. The use of alkali metal iodide to precipitate by-products and silver ions is not taught or disclosed in the prior art." Bhatt Dec. Ex. 3, Office Action at 4. The applicants failed to respond to the Examiner's statement and suggest that the claims were not so limited. Therefore, the claims are limited to processes that include the use of sodium iodide and/or potassium iodide to remove compound II, the by-products of compound II, and silver ions. Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 979 (Fed. Cir. 1999) (Examiner's Statement of Reasons for Allowance and Elkay's failure to respond to the Examiner's Statement relevant to claim construction); Ortho-McNeil Pharmaceutical, Inc. v. Kali Laboratories, Inc., 482 F. Supp. 2d 478, 498 (D.N.J. 2007) (examiner's understanding of claim limitation and applicant's failure to correct that understanding were intrinsic evidence relevant to claim construction).

In sum, the claim language, specification, and prosecution history support a construction of claim 1 that includes the following step:

> **addition of sodium iodide and/or potassium iodide to convert compound II, the by-products of compound II, and silver ions to their iodide compounds followed by removal of the iodide compounds.**

III.

FRESENIUS IS ENTITLED TO SUMMARY JUDGMENT OF NON-INFRINGEMENT AS A MATTER OF LAW BECAUSE SANOFI IS PRECLUDED FROM RELYING ON THE DOCTRINE OF EQUIVALENTS

A. Sanofi Admits that Fresenius Does Not Literally Infringe

In its interrogatory responses, Sanofi only asserts infringement under the doctrine of equivalents and does not assert that Fresenius literally infringes claim 1 of the '961 patent. Bhatt Dec. Ex. 1, Sanofi Response to Interrogatory No. 5. [redacted] Sanofi's opposition offers no response to Fresenius's argument that it will not literally infringe. [redacted] and Fresenius is therefore entitled to judgment as a matter of law that Sanofi cannot prove that Fresenius will literally infringe.

B. The Applicants Chose to Narrowly Claim Their Invention and Describe It as the Solution to the Problem with the Prior Art Process and Cannot Now Rely on the Doctrine of Equivalents to Expand the Claims [redacted]

1. The applicants claimed a process in which sodium iodide and/or iodide is used to remove compound II, the by-products of compound II, and silver ions

In this case, the applicants chose to narrowly claim their alleged invention and included a step in which sodium iodide and/or potassium iodide is added to remove compound II, the by-products of compound II, and silver ions. "Members of the public were therefore justified in relying on this specific language in assessing the bounds of the claim. . . to now say the claims include [redacted] under the doctrine of equivalents would

unjustly undermine the reasonable expectations of the public." Freedman Seating Co. v. American Seating Co., 420 F.3d 1350, 1362 (Fed. Cir. 2005).

"Here, the patent[] contain[s] a distinct limitation, which was part of the bargain when the patent issued. This court cannot overlook that limitation or expand the doctrine of equivalents beyond its purpose to allow recapture of subject matter excluded by a deliberate and foreseeable claim drafting decision." Planet Bingo, 472 F.3d at 1344; Tip Systems, LLC v. Phillips & Brooks/Gladwin, Inc., 529 F.3d 1364, 1380 (Fed. Cir.), cert. denied, 129 S. Ct. 629 (2008); Sage Products, Inc. v. Devon Industries, Inc., 126 F.3d 1420, 1425 (Fed. Cir. 1997) ("[A]s between the patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to seek protection for this foreseeable alteration of its claimed [process]."); Pharmacia & Upjohn Co. v. Mylan Pharmaceuticals, Inc., 5 F. Supp. 2d 399, 406 (N.D. W.Va. 1998), aff'd, 170 F.3d 1373 (Fed. Cir. 1999) ("Upjohn had the opportunity to present claims to the PTO in which the lactose excipient was defined as Upjohn now advocates . . . Upjohn's decision to limit its claims specifically to spray-dried lactose is a choice upon which the public was entitled to rely.").

Based upon the applicants' choice of narrow claim language, the doctrine of equivalents is not available to expand the claims to encompass the Fresenius process, [redacted]

Sanofi's argument that Fresenius cannot rely on Sage Products (Opp. at 13-14) is without merit. First, Fresenius relies on Sage Products and its progeny for the following proposition: "where a patentee has claimed an invention narrowly, as in this case, there may not be infringement under the doctrine of equivalents . . . This is the case, because, when applied broadly, the doctrine of equivalents 'conflicts with the definitional and public-notice functions of

the statutory claiming requirement.'" Bickerstaff v. Auto Top, Inc., No. 98-106, 1999 U.S. Dist. LEXIS 8021, at *12-13 (W.D. Mich. May 24, 1999) (quoting Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29 (1997)). The court in Pharmacia & Upjohn, 5 F. Supp. 2d at 406, similarly held "Upjohn's decision to limit its claims specifically to spray-dried lactose is a choice upon which the public was entitled to rely. Accordingly, the consequences of this choice should fall on Upjohn." Thus, courts applying Sage Products have focused on the important role that the claims play in notifying the public of the scope of the patentee's alleged invention.

Second, even if Sanofi's argument that Sage Products only applies in cases involving vitiation were correct, vitiation applies in this case and provides an additional basis for holding that as a matter of law Sanofi cannot rely on the doctrine of equivalents. [redacted] Warner-Jenkinson, 520 U.S. at 29 ("It is important to insure that the application of the doctrine . . . is not allowed such broad play as to effectively eliminate that element in its entirety.").

Sanofi also misrepresents Fresenius's argument that the narrowly drafted claim should not be expanded to reach processes such as Fresenius's. Fresenius did not argue that "no claim identifying a specific compound would ever be entitled to cover an equivalent compound." Sanofi Opp. at 14. To the contrary, Fresenius argued that on the facts of this case, the applicants' choice of narrow claim language taken together with the applicants' description of the alleged invention in the specification (see Section III.B.2. below), preclude reliance on the doctrine of equivalents as a matter of law.

2. The applicants describe the use of sodium iodide and/or potassium iodide as the solution to the problem with the prior art process

The '961 patent applicants describe their alleged invention as a very specific solution to a very specific problem with the prior art process. The applicants first identify the problem with

the prior art process: the presence of compound II, the by-products of compound II, and silver ions. Bhatt Dec. Ex. 2, '961 patent, lines 43-48. The applicants then explain that their alleged invention lies in the following discovery: the addition of sodium iodide and/or potassium iodide converts compound II, the by-products of compound II, and silver ions to their iodide compounds and the iodide compounds can then be removed. Bhatt Dec. Ex. 2, '961 patent, col. 2, lines 27-36, 42-45. By virtue of the way that the applicants chose to claim their alleged invention (see Section III.B.1. above) and the way that they chose to describe their alleged invention as the solution to the problem with the prior art process, claim 1 cannot be expanded to cover processes that do not use the claimed solution (sodium iodide and/or potassium iodide) to solve the problem with the prior art process (the need to remove compound II and the by-products of compound II). Cultor, 224 F.3d at 1331 ("The purpose of the invention is the removal of bitter taste caused by citric acid. To enlarge the scope to cover other acids, when no bitter taste and no citric acid are present, by use of a well known purification mechanism, is not available through the doctrine of equivalents."); Augustine Medical, Inc. v. Gaymar Industries, Inc., 181 F.3d 1291, 1299-1300 (Fed. Cir. 1999) (specification criticized, and discussed disadvantages of, prior art products and described alleged invention as solution to those problems and "primary advantage over the prior art"); O.I. Corp. v. Tekmar Co. Inc., 115 F.3d 1576, 1584 (Fed. Cir. 1997) (Federal Circuit refused to extend the claims under the doctrine of equivalents to reach accused device because of limiting disclosures and statements made in patent specification).

The facts in this case are very similar to the facts in Cultor, 224 F.3d 1328. In that case, the inventors explained in the specification that the prior art process resulted in a product that had a bitter taste. 224 F.3d at 1330. In their description of the invention, the inventors explained that the bitter taste was due to the use of citric acid in the prior art process and in the claimed

invention an ion exchange column was used to remove the citric acid. 224 F.3d at 1330. The claims included the use of an ion exchange column to remove the citric acid. The accused infringer used phosphoric acid instead of citric acid so the product that resulted from its process did not have a bitter taste. The accused infringer used an ion exchange column in its process in order to remove phosphoric acid, not citric acid. 224 F.3d at 1331. The Federal Circuit in Cultor held that "[t]o enlarge the scope to cover other acids, when no bitter taste and no citric acid are present, by use of a well known purification mechanism, is not available through the doctrine of equivalents." 224 F.3d at 1331.

In this case, the prior art process did not remove compound II, the by-products of compound II, and silver ions. The '961 patent applicants describe their invention as a solution to that problem and explain that these compounds are removed by adding sodium iodide and/or potassium iodide. [redacted]

The step in which sodium iodide and/or potassium iodide is added is the only description in the specification that differentiates the claimed process from the prior art process. In other words, all of the other steps are old and only the addition of sodium iodide and/or potassium iodide in the next to the last step of the process to perform the claimed function (removal of compound II, the by-products of compound II, and silver ions) is new. Thus, this new step is critical to the alleged invention and any process that does not include the claimed compounds and the claimed functions is outside of the scope of the claims.

Sanofi mischaracterizes Fresenius's reliance on Salazar v. Procter & Gamble Co., 414 F.3d 1342 (Fed. Cir. 2005; Union Oil of California v. Atlantic Richfield Co., 208 F.3d 989 (Fed. Cir. 2000); and Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F.3d 1547 (Fed. Cir. 1997). Opp. at 12, 14-15. Fresenius relied on this cases in support of its claim construction, not its discussion of the doctrine of equivalents. Opening Mem. at 8.

In sum, the applicants' decision to narrowly claim their process for preparing oxaliplatin and require the use of sodium iodide and/or potassium iodide to remove compound II, the by-products of compound II, and silver ions and the applicants' description of their invention in the specification as the solution to the problem with the prior art process bar them as a matter of law from relying on the doctrine of equivalents to expand the claim scope to encompass Fresenius's process.

IV.

FRESENIUS IS ENTITLED TO SUMMARY JUDGMENT OF NON-INFRINGEMENT FOR THE ADDITIONAL REASON THAT SANOFI HAS NOT RAISED A GENUINE ISSUE OF MATERIAL FACT THAT [redacted]

Claim 1 as properly construed requires the addition of sodium iodide and/or potassium iodide to convert [a] compound II, [b] the by-products of compound II, and [c] silver ions to their iodide compounds followed by removal of the iodide compounds. See Section II above. In order to prove infringement under the doctrine of equivalents, Sanofi must prove that [redacted] performs substantially the same function, in substantially the same way, to achieve substantially the same result. Warner-Jenkinson, 520 U.S. at 39-40. The alternative test for infringement under the doctrine of equivalents asks whether there are "insubstantial differences" between the claimed process and the accused process. Canton Bio-Medical, Inc. v. Integrated Liner Technologies, Inc., 216 F.3d 1367, 1369 (Fed. Cir. 2000) ("Processes are equivalent, in

terms of the law of patent infringement, when there is no substantial difference between the patented process and the accused process.").

A. Fresenius Will Not Infringe Under the Doctrine of Equivalents Because [redacted]

This case is very similar to the Federal Circuit's decision in Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc., 98 F.3d 1563, 1574 (Fed. Cir. 1996). In that case, the claim required "the function of removing the electrostatic contamination that is formed at low temperatures." 98 F.3d at 1574. The accused infringer's process, however, was "conducted without the formation of electrostatic contamination," because there was no cooling step. 98 F.3d at 1574. The Federal Circuit concluded "thus electrostatic attraction does not form and is not removed as claim 1 requires. This is not an insubstantial difference and precludes infringement of claim 1 under the doctrine of equivalents." 98 F.3d at 1574 (internal citation omitted). [redacted]

The cases relied upon by Sanofi (Opp. at 7-10) do not require a different result. None of the cases that Sanofi cites involved a patentee that was legally foreclosed from relying on the

doctrine of equivalents because it had narrowly claimed and described its invention. In addition, the Supreme Court in Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605, 609 (1950), held that "[w]hat constitutes equivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case." As demonstrated above, the "particular circumstances" in this case support a finding of non-infringement.

V.

SANOFI'S CROSS-MOTION SHOULD BE DENIED BECAUSE SANOFI HAS FAILED TO COME FORWARD WITH EVIDENCE THAT

[redacted]

"The present case is one in which the claims mean what they say. Their effectiveness cannot be extended to cover the [Fresenius process], which [does] not meet the claim limitations." London, 946 F.2d at 1538.

[redacted]

A conclusion of non-infringement under the doctrine of equivalents is further supported by Fresenius's efforts to design around the patent. O'Malley Dec. Ex. D[4]; Roton Barrier, Inc. v. Stanley Works, 79 F.3d 1112, 1127 (Fed. Cir. 1996) ("designing around provides an inference of no infringement under the doctrine"); Dolly, Inc. v. Spalding & Evenflo Cos., Inc., 16 F.3d 394, 400 (Fed. Cir. 1994) ("Moreover, Evenflo appropriately designed around the claimed invention.").

Finally, the Federal Circuit has cautioned against the use of the doctrine of equivalents in the manner suggested by Sanofi:

> Application of the doctrine of equivalents is the exception, however, not the rule, for if the public comes to believe (or fear) that the language of patent claims can never be relied on, and that the doctrine of equivalents is simply the second prong of every infringement charge, regularly available to extend protection beyond the scope of the claims, then claims will cease to serve their intended purpose. Competitors will never know whether their actions infringe a granted patent.

London, 946 F.2d at 1538.[5]

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[4] O'Malley Dec. Ex. D was filed on February 9, 2009 with Sanofi's opposition memorandum.

[5] Recently, Chief Judge Michel of the Federal Circuit had the following comments concerning the limited applicability of the doctrine of equivalents:

> **Chief Judge Michel**: Well I certainly agree with the idea that the Doctrine of Equivalents should be a special equity type tool used only in fairly rare and compelling circumstances. It's not like an alternative to literal infringement that should be available in every case. My own sense is that the Doctrine of Equivalents has been largely abandoned. For example, we very rarely get Doctrine of Equivalents issues on appeal any more. We use to get lots.
>
> **Chief Judge Michel**: I don't think so. I think the Markman regime if I can call it that made people so aware of the public notice function of peripheral claims. There are usually many, many claims in a patent, as you know, and often there are many patents in a litigation that people concentrated their litigation efforts on trying to get a favorable claim construction from which ever side they were on and didn't pay much attention to the Doctrine of Equivalents as some sort of magic bullet to get them out of trouble. So my impression is that Doctrine of Equivalents is kind of dried up for the most part. It's just not a live central part of most infringement cases any more.

VI.

FRESENIUS HAS NOT ADMITTED THAT ITS PROCESS INCLUDES EVERY OTHER STEP IN THE '961 PATENT PROCESS

A. To Prevail on its Non-Infringement Defense, Fresenius Need Only Demonstrate that Its Process Does Not Include One Claim Limitation

Sanofi's suggestion that Fresenius has admitted that its process includes every other stop in the claim 1 process is incorrect. Opp. at 1. In its opening memorandum, Fresenius demonstrated that its process did not include a step of the claimed process. As the accused infringer, that is all Fresenius has to do in order to prevail. Carroll Touch, Inc. v. Electro Mechanical Systems, Inc., 15 F.3d 1573, 1576 (Fed. Cir. 1993) ("A claim covers an accused [process] if the [process] embodies every limitation of the claim, either literally or by an equivalent."); Spectrum Int'l, 164 F.3d at 1379 (if the accused product fails to meet even one claim limitation, it cannot infringe the claim).

In response to this incorrect argument and in opposition to Sanofi's cross-motion, Fresenius submits that there are other limitations of the claim that are not met by the Fresenius

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> **Chief Judge Michel**: I haven't seen any cases where the result seemed unfair to the patent owner whose patent was clearly not infringed as a literal matter or where there is some strong equity on the side of the patent owner. Usually the claims are so numerous and so varying in scope that it's hard to feel sympathetic for what was left excluded because the main impression I get looking at most patents that I see is that the broadest claims are way too broad and may well be invalid under 103 or other ground and obviously the drafter was trying to capture everything he could possibly get away with. So the need to resort to the Doctrine of Equivalents in order to have some sort of supposedly equitable or fair result seems to be now quite the rare case as a result of claim drafting practices of more recent years and also the whole Markman regime which is not I guess 12 years or so in existence. So I agree with you that the Doctrine of Equivalents is sort of hard to square with some of the limits imposed on it, but I don't think that it's unavailable where it's really needed. I just think that it's rarely, really needed.

Excerpts of "A Conversation with Chief Judge Paul Michel" conducted by Professor Doug Lichtman (available at http://www.ipcolloquium.com/Programs/4.html).

process. [redacted]

[redacted]

B. Claim 1 of the '961 Patent Requires that the Steps be Performed Sequentially

According to the language of claim 1, sodium iodide and/or potassium iodide are added to remove compound II, the by-products of compound II, and silver ions from an intermediate compound:

> 1. A process of preparing a cis-platinum (II) complex of a 1,2-cyclohexanediamine isomer designated by a general formula (I) . . .
>
> which comprises . . . adding to the solution sodium iodide and/or potassium iodide to convert the unreacted compound (II), the by-products of the compound (II) and an unreacted silver ion to their iodine compounds followed by the removal thereof and thereafter adding the corresponding organic dibasic acid of the formulae (V), (VI), (VII), (VIII), (IX) and (X) to the remaining platinum complex.

Only after this step is performed, is a dibasic acid then added to the intermediate compound to form oxaliplatin. Bhatt Dec. Ex. 2, '961 patent, Claim 1. Thus, in the claimed process the intermediate compound is being purified.

The plain language of the claim requires a sequence of steps: (1) the sodium iodide and/or potassium iodide convert compound II, the by-products of compound II, and silver ions to their iodide compounds followed by their removal; and (2) the dibasic acid is added thereafter to the platinum complex that is remaining after the iodide compounds in the previous step have been removed. "[T]he sequential nature of the claim steps is apparent from the plain meaning of the claim language and nothing in the written description suggests otherwise." Mantech Environmental Corp. v. Hudson Environmental Services, 152 F.3d 1368, 1376 (Fed. Cir. 1998); E-Pass Technologies, Inc. v. 3COM Corp., 473 F.3d 1213, 1222 (Fed. Cir. 2007)) ("because the language of most of the steps of its method claim refer to the completed results of the prior step, E-Pass must show that all of those steps were performed in order.").

C. Fresenius Will Not Literally Infringe Claim 1 [redacted]

D. Fresenius Will Not Infringe Under the Doctrine of Equivalents [redacted]

As explained above in Section III, Sanofi is legally foreclosed from relying on the doctrine of equivalents. [redacted] There is, therefore, a substantial difference between the claimed process and the Fresenius process. Burgess Dec. ¶¶25-27. [redacted] Burgess Dec. ¶¶25-27. For this additional, separate, and independent reason, Fresenius is therefore entitled to entry of judgment as a matter of law that Sanofi cannot prove infringement under the doctrine of equivalents.

CONCLUSION

For the foregoing reasons, and the reasons in its opening memorandum, Fresenius respectfully requests that the Court grant its motion for summary judgment of non-infringement of the '961 patent and deny Sanofi's cross-motion for summary judgment of infringement.

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Respectfully submitted,

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